Notice of Allowability	Application No.	Applicant(s)	
	10/817,239	HACK ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicant's reply of 3/6/2006*.

2. ☒ The allowed claim(s) is/are *1-5 and 16-18 [renumbered as 1-3]*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

Applicant's election of Group I in the reply filed on 3/6/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Weide on 4/13/2006.

Amendments to the Claims

Claim 2. (Currently amended) The tablet according to claim 1 containing about 20-30 mg indium sulfate.

Claim 3. (Currently amended) The tablet according to claim 1 containing about 100 µg zinc oxide, about 100 µg copper (II) oxide, about 100 µg magnesium oxide, about 100 µg potassium iodide, about 100 µg selenium amino acid chelate, about 100 µg chromium amino acid chelate and about 100 µg manganese amino acid chelate.

Claim 4. (Currently amended) The tablet according to claim 1 containing about 5% by weight cocoa powder.

Claim 16. (Currently amended) A method for producing a tablet for oral administration of indium comprising the steps of:

providing indium sulfate, caffeine and a portion of cocoa powder in a granulator;

providing ethyl cellulose and isopropyl alcohol in a mixer and mixing the ethyl cellulose and isopropyl alcohol;

adding the mixed ethyl cellulose and isopropyl alcohol to said granulator;

granulating a mixture of said indium sulfate, said caffeine, said portion of cocoa powder, said ethyl cellulose and said isopropyl alcohol;

removing substantially all of said isopropyl alcohol by drying said mixture in an oven, resulting in a cake;

grinding said cake through a mill to provide a granulate;

adding dicalcium phosphate and zinc oxide to said granulate;

screening said granulate with dicalcium phosphate and zinc oxide to provide a screened mixture of said granulate, dicalcium phosphate and zinc oxide; and

forming said screened mixture into said tablet; wherein

said indium sulfate, caffeine, cocoa powder, ethyl cellulose and zinc oxide are present in sufficient amounts so that said tablet contains about 10-50 mg indium sulfate, about 4-20 mg caffeine, about 2-10% by weight cocoa powder, about 5-10% by weight ethyl cellulose and about 50-150 μg zinc oxide.

Claim 17. (Currently amended) A method of producing a tablet for oral administration of indium comprising the steps of:

(1) providing indium sulfate, caffeine and a first portion of cocoa powder in a granulator;

providing ethyl cellulose and isopropyl alcohol in a mixer and mixing the ethyl cellulose and isopropyl alcohol;

adding the mixed ethyl cellulose and isopropyl alcohol to said granulator;

granulating a mixture of said indium sulfate, said caffeine, said first portion of cocoa powder, said ethyl cellulose and said isopropyl alcohol;

removing substantially all of said isopropyl alcohol by drying said mixture in an oven, resulting in a cake;

grinding said cake through a mill to provide a granulate;

adding dicalcium phosphate and zinc oxide to said granulate;

screening said granulate with dicalcium phosphate and zinc oxide to provide a screened mixture of said granulate, dicalcium phosphate and zinc oxide;

(2) providing a second portion of cocoa powder;

mixing said second portion of cocoa powder with cellulose;

screening said second portion of cocoa powder and said cellulose with magnesium stearate through a screen;

adding the screened second portion of cocoa powder, said cellulose and said magnesium stearate to a blender;

adding copper oxide, selenium amino acid chelate, chromium amino acid chelate, manganese amino acid chelate, magnesium oxide, potassium iodide, microcrystalline cellulose, cellulose gum, silica and said screened mixture of step (1) to said blender, forming a pre-tablet mixture;

blending said pre-tablet mixture; and

forming the blended pre-tablet mixture into tablets for storage in an air-tight container;

wherein said indium sulfate, caffeine, first and second portions of cocoa powder, ethyl cellulose and zinc oxide are present in sufficient amounts so that said tablet contains about 10-50 mg indium sulfate, about 4-20 mg caffeine, about 2-10% by weight cocoa powder, about 5-10% by weight ethyl cellulose and about 50-150 µg zinc oxide.

Amendment to the Specification

Specification page 7, line 15: delete "at".

The following is an examiner's statement of reasons for allowance: the claimed invention, as amended above, is directed to an indium-containing tablet and methods for producing an indium-containing tablet. The tablet invention requires the tablet to

contain about 10-50 mg indium sulfate, about 4-20 mg caffeine, about 2-10 wt% cocoa powder, about 5-10 wt% ethyl cellulose, about 50-150 µg zinc oxide, about 50-150 µg copper (II) oxide, about 50-150 µg magnesium oxide, about 50-150 µg potassium iodide, about 50-150 µg selenium amino acid chelate, about 50-150 µg chromium amino acid chelate and about 50-150 µg manganese amino acid chelate. The method inventions for producing an indium-containing tablet require specific, multiple steps, wherein indium sulfate, caffeine, cocoa powder, ethyl cellulose and zinc oxide are provided in sufficient amounts so that the obtained tablet contains about 10-50 mg indium sulfate, about 4-20 mg caffeine, about 2-10% by weight cocoa powder, about 5-10% by weight ethyl cellulose and about 50-150 µg zinc oxide.

The prior art, taken as a whole, fails to adequately disclose or suggest the presently claimed invention. Bonadio (US 4,591,506) discloses oral indium supplements, but one of the disclosed uses of said supplements is for "anti-caffeinism" (column 3, line 24). Use of 10-50 mg indium in conjunction with 4-20 mg caffeine, in addition to the various other ingredients required in the instant invention, is therefore not fairly suggested by Bonadio. Further, GB 2,384,984 discloses palliation of caffeine withdrawal symptoms by combining 10-100 mg caffeine/dose (page 5, second full pargraph) with one or more vitamins and/or minerals (claim 5 & all of page 4). The disclosed amount of such vitamins and/or minerals is the RDA, Recommended Daily Allowance (page 4, last paragraph; page 5, last full paragraph). Given that the RDA for

indium is not well established and the instant invention recites less than the RDA for many of the ingredients (e.g. zinc, copper, magnesium), not to mention the lack of motivation to select all the other claimed ingredients at the claimed amounts *in combination*, GB 2,384984, either alone or taken with other prior art references, fails to suggest the claimed invention as a whole.

For these reasons, the prior art fails to adequately disclose or suggest the claimed invention, and the claimed invention as a whole is deemed to be allowable. Remaining references listed on the attached PTO-892 are cited to further show the state of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Sreeni Padmanabhan, can be reached on **(571)272-0629**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
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